JUL 0 8 2003

K031453

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Name

TERUMO® SurGuard 2™ Safety Needle or similar proprietary name

Classification Name

Hypodermic Single Lumen Needle (880.5570)

Classification: Class II 80 FMI

Common Name

Hypodermic needle with safety sheath or needle with needle protection device

B. Intended Use

The TERUMO® SurGuard 2™ SAFETY NEEDLE device is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdraw of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

C. Device Description

The SurGuard 2™ Safety Needle consists of a hypodermic needle with a hinged safety sheath attached to the connector hub. The safety sheath contains a locking mechanism which is activated when the sheath is manually pressed over the needle immediately after use and just prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with a one-handed operation by pressing the sheath against a firm surface. The locking mechanism is located at a designated position within the body of the short or long sheath appropriate for the needle size it is to contain. The needle gauge sizes are 18gauge to 25gauge and the needle lengths are 5/8" to 1 ½". The hinge feature allows the user to set the sheath to the desired position for use. For user convenience, when the needle is in the "bevel up" position the sheath is located to the right. The SurGuard 2™ Safety Needle will be individually packaged and sterilized as a safety needle only or as a safety needle with attached Terumo syringe (as cleared under K771205 and K980181).

D. Substantial Equivalence

The SurGuard 2™ Safety Needle without or with syringe attached is substantially equivalent to:

1. K923127 - SurGuard Needle/Syringe with Needle Protection device manufactured by Portex, Inc.
2. K771203 - Terumo Hypodermic Needle
3. K771205 & K980181 - Terumo Hypodermic Syringe

All of these cleared devices serve as predicates for the device which is subject of this 510k.

E. Principle of Operation and Technology

The Terumo SurGuard 2™ Safety Needle, the Surguard device manufactured by Portex, Inc (K923127), the Terumo Hypodermic Needles (K771203) and Terumo Hypodermic Syringes (K771205 and K980181) are all operated manually.

F. Materials

The materials used for the hypodermic needle and syringe portion of the SurGuard 2™ Safety Needle are identical to the materials used for the cleared Terumo Hypodermic Needles (K771203) and Terumo Hypodermic Syringe (K771205 and

K980181). The material selected for the safety feature is the same type of material used for the sheath of the Surguard predicate (K923127). Any differences in materials between the SurGuard 2™ Safety Needle and the Surguard predicate raise no new issues of safety and effectiveness.

G. Specifications

Product Descriptions
18 gauge x 1" safety needle
18 gauge x 1 ½" safety needle
19 gauge x 1" safety needle
19 gauge x 1 ½" safety needle
20 gauge x 1" safety needle
20 gauge x 1 ½" safety needle
21 gauge x 1" safety needle
21 gauge x 1 ½" safety needle
22 gauge x 1" safety needle
22 gauge x 1 ½" safety needle
23 gauge x 1" safety needle
23 gauge x 1 ½" safety needle
25 gauge x 5/8" safety needle
25 gauge x 1" safety needle
25 gauge x 1 ½" safety needle
1cc/ml syringe with 25 gauge x 5/8" safety needle
3cc/ml syringe with 20 gauge x 1" safety needle
3cc/ml syringe with 20 gauge x 1 ½" safety needle
3cc/ml syringe with 21 gauge x 1" safety needle
3cc/ml syringe with 21 gauge x 1 ½" safety needle
3cc/ml syringe with 22 gauge x 1" safety needle
3cc/ml syringe with 22 gauge x 1 ½" safety needle
3cc/ml syringe with 23 gauge x 1" safety needle
3cc/ml syringe with 25 gauge x 5/8" safety needle
3cc/ml syringe with 25 gauge x 1" safety needle
5cc/ml syringe with 20 gauge x 1" safety needle
5cc/ml syringe with 20 gauge x 1 ½" safety needle
5cc/ml syringe with 21 gauge x 1 ½" safety needle
10cc/ml syringe with 20 gauge x 1" safety needle
10cc/ml syringe with 20 gauge x 1 ½" safety needle
10cc/ml syringe with 21 gauge x 1" safety needle

H. Performance

The following tests were performed on the SurGuard 2™ Safety Needle:

- Activation Force
- Deactivation Force
- Puncture Resistance
- Sheath Removal Force
- Collar Removal Force
- Sheath Radial Force
- Protector Fit
- Simulated Use Study

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

The performance of the SurGuard 2™ Safety Needle submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the legally marketed predicate devices.

I. Additional Safety Information

Manufacturing controls include visual, functional, and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137-1994 Medical Devices – Validation and Routine Control of Radiation Sterilization. The SurGuard 2™ Safety Needle is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The Terumo SurGuard 2™ Safety Needle is classified as Externally Communicating Device, Blood Path Indirect, Limited Duration of Contact (< 24 hr). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

J. Conclusion

The SurGuard 2™ Safety Needle without or with syringe attached is substantially equivalent to:

4. K923127 - SurGuard Needle/Syringe with Needle Protection device manufactured by Portex, Inc.
5. K771203 - Terumo Hypodermic Needle
6. K771205 & K980181 - Terumo Hypodermic Syringe

Differences between the devices do not raise any significant issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared: May 2, 2003

Prepared By: Barbara Smith
Sr. Regulatory Affairs Specialist

Prepared For: Terumo Medical Corporation
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 8 2003

Ms. Barbara Smith
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland, 21921

Re: K031453
Trade/Device Name: TERUMO® Surguard 2 ™Safety Needle
Regulation Number: 21 CFR 880.5570, 21 CFR 880.5860
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI, MEG
Dated: May 2, 2003
Received: May 8, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

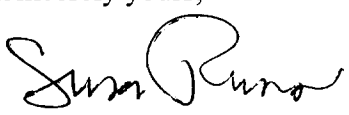
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Terumo Medical Corporation
Section: Intended Use Statement

510(k) Number (if known): K031453

Device Name: TERUMO® SurGuard 2™ Safety Needle

Indications For Use:
The TERUMO® SurGuard 2™ SAFETY NEEDLE device is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdraw of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031453